

The social phobia psychotherapy research network

Submission date 22/06/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/08/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The social phobia psychotherapy research network

Acronym

SOPHO-NET

Study objectives

Differential efficacy of short-term psychodynamic psychotherapy (STPP) and cognitive-behavioral therapy (CBT) in social phobia therapy - named hypothesis A1

The first add-on study (named C1) of this multicentre trial will be studying genetic polymorphisms in patients with social phobia who are treated with STPP and CBT.

The second add-on study (named C2) of this multicentre trial will be studying the neural functional and structural changes in patients with social phobia who are treated with STPP and CBT.

The third add-on study (named C3) of this multicentre trial will be studying the attachment characteristics as differential predictors of treatment outcome in 128 patients with social phobia who are treated with STPP and CBT.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical Faculty of the University of Goettingen, 06/12/2006

Study design

Randomized controlled multicenter trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Social phobia (social anxiety disorder)

Interventions

Manualized short-term psychodynamic psychotherapy (STPP) versus manualized cognitive-behavioral therapy (CBT)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

For A1, primary outcome is no diagnosis of SP according to the SCID-I DSM-IV and the Liebowitz Social Anxiety Scale

For C1, the primary outcome will be, that the psychotherapy outcome is associated with genetic variation in the serotonin transporter (SERT) gene (directed: L12 higher pre-post difference in the Liebowitz Social Anxiety Scale [LSAS])

For C2, primary outcomes will include normalisation of neural structural and functional abnormalities after successful treatment

For C3, primary outcomes will be whether patients reveal a secure organized attachment; representation will reach a better outcome than those with insecure features and/or disorganized states of mind

Secondary outcome measures

For A1, secondary outcomes will include:

1. Social anxiety (Social Phobia and Anxiety Inventory [SPAI])
2. Depression (Beck Depression Inventory [BDI])
3. Interpersonal problems (IIP)
4. Self-image
5. Quality of life or social functioning (short-form-12 questionnaire [SF-12])
6. Costs and utilities of the treatments

For C1, the secondary outcome will be, that the severity of social phobia is linked with genetic variation in SERT gene (directed: S10 higher LSAS at baseline)

For C2 secondary outcome will include specificity of neural structural and functional abnormalities in social phobia

For C3, secondary outcome will include whether a self-reported attachment will significantly change after successful therapy indicating increased security. This will be tested by using the Experiences in Close Relationships-Revised (ECR-R) instrument within the entire sample (n = 512)

Overall study start date

01/10/2006

Completion date

01/10/2009

Eligibility

Key inclusion criteria

1. Diagnosis of social phobia (SP) according to the Structured Interview for Diagnostic and Statistical Manual of Mental Disorders - fourth edition [SCID-I DSM-IV]) and primary diagnosis of social phobia according to the Liebowitz Social Anxiety Scale >302
2. Aged 18 to 59 versus 60 to 70 years
4. Participants must be made up of 60% women; 40% men

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

512

Key exclusion criteria

1. Psychotic disorder
2. Risk of self-harm
3. Acute substance related disorder
4. Personality disorders except for cluster C
5. Organic mental disorder
6. Severe medical conditions
7. Concurrent psychotherapeutic or psychopharmacological treatment

Date of first enrolment

01/10/2006

Date of final enrolment

01/10/2009

Locations**Countries of recruitment**

Germany

Study participating centre

von Sieboldstrasse 5

Goettingen

Germany

37075

Sponsor information

Organisation

Ministry for Development and Research (Bundesministerium für Bildung und Forschung [BMBF])
(Germany)

Sponsor details

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Sponsor type

Government

Website

<http://www.bmbf.de>

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/12/2013		Yes	No
Results article	results	19/01/2016		Yes	No